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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18-11]

Health Fit Pharmacy; Decision and Order

On November 15, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Health Fit Pharmacy (Respondent), of Houston, Texas. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration No. FH1729942 on the ground that he has "no state authority to handle controlled substances." Order to Show Cause, at 1 (citing 21 U.S.C. § 824(a)(3)). For the same reason, the Order also proposed the denial of any of Respondent's "applications for renewal or modification of such registration and any applications for any other DEA registrations." *Id.*

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Respondent is the holder of Certificate of Registration No. FH1729942, pursuant to which it is authorized to dispense controlled substances as a retail pharmacy in schedules II through V, at the registered address of 1307 Yale Street, Suite H, Houston, Texas. *Id.* The Order also alleged that this registration does not expire until October 31, 2018. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order alleged that on September 15, 2017, the Texas State Board of Pharmacy (TSBP) "suspended" Respondent's Texas pharmacy license, and Respondent is therefore "without authority to practice pharmacy or handle controlled substances in the State of Texas, the [S]tate in which [it is] registered with the DEA." *Id.* at 2. Based on its "lack of authority to [dispense] controlled substances in . . .

Texas,” the Order asserted that “DEA must revoke” Respondent’s registration. *Id.* (citing 21 U.S.C. § 824(a)(3); 21 CFR 1301.37(b)).

The Show Cause Order notified Respondent of (1) its right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, (2) the procedure for electing either option, and (3) the consequence for failing to elect either option. *Id.* (citing 21 CFR § 1301.43). The Order also notified Respondent of its right to submit a corrective action plan. *Id.* at 2-3 (citing 21 U.S.C. § 824(c)(2)(C)).

On December 4, 2017, Respondent, through counsel, filed a letter requesting a hearing on the allegations. Letter from Respondent’s Counsel to Hearing Clerk (dated Nov. 30, 2017) (hereinafter, Hearing Request). In this letter, Respondent “objects to the cancellation of Health Fit Pharmacy[’s DEA] controlled substance registration” for two reasons. First, Respondent states that, “although temporar[il]y suspended,” it “maintains an active license.” *Id.* at 1. Second, Respondent “expects to prevail” in a “final contested hearing regarding the temporary suspension of this license on the merits . . . scheduled for February, 2018.” *Id.*

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ). On December 4, 2017, the CALJ ordered the Government to file “evidence to support the allegation that the Respondent lacks state authority to handle controlled substances” and file “any Government motion for summary disposition” no later than December 15, 2017. Order Directing the Filing of Government Evidence of Lack of State Authority Allegation and Briefing Schedule, at 1-2. The CALJ also directed Respondent to file its response to any summary disposition motion no later than December 29, 2017. *Id.* at 2.

On December 15, 2017, the Government filed its Motion for Summary Disposition. In its Motion, the Government argued that it is undisputed that Respondent lacks authority to handle controlled substances in Texas because the TSBP suspended Respondent's Texas medical license on September 15, 2017. Government's Motion for Summary Disposition (hereinafter Government's Motion or Govt. Mot.) at 2-3; TSBP Temporary Suspension Order #A-16-008-BS1 (Government Exhibit (GX) 2 to Govt. Mot. or "Sept. 15, 2017 TSBP Order"). The Government also noted that, in its Hearing Request, Respondent did not dispute that the TSBP had suspended Respondent's pharmacy license. Govt. Mot. at 3 n.1. The Government further argued that, "[a]bsent authority by the State of Texas to dispense controlled substances, Respondent is not authorized to possess a DEA registration in that state." *Id.* at 3. Lastly, the Government argued that under Agency precedent, revocation is warranted even where a State has temporarily suspended a practitioner's state authority with the possibility of future reinstatement. *Id.* at 3-4 (citations omitted). As support for its summary disposition request, the Government attached, *inter alia*, a copy of the TSBP's September 15, 2017 Order directing that Respondent's license "is hereby temporarily suspended . . . effective immediately and shall continue in effect, pending a contested hearing on disciplinary action against the suspended license." GX 2 to Govt. Mot., at 14.

In its responsive pleading, Respondent did not dispute that it "maintains a[n] active suspended license" in the State of Texas. Respondent's Dec. 29, 2017 Response to Government's Motion for Summary Disposition (hereinafter, Resp. Br.), at 2. Instead, Respondent argued that "the merits of the temporary suspension is being disputed by" Respondent and that the Government filed its Motion "prematurely in li[ght] of the fact that a final order . . . has not been entered." *Id.* at 2-3. Finally, Respondent argued that "[t]he effect

of” the Government’s motion for summary disposition “is to circumvent contested litigation procedure.” *Id.* at 3.

After considering these pleadings, the CALJ issued an order recommending that I find that there was no dispute over the fact that “Respondent lacks state authority to handle controlled substances in Texas.” Order Granting the Government’s Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (R.D.), at 6. As a result, the CALJ granted the Government’s motion for summary disposition and recommended that I revoke Respondent’s DEA registration and deny any pending renewal applications. *Id.*

Neither party filed exceptions to the CALJ’s Recommended Decision. Thereafter, the record was forwarded to my Office for Final Agency Action. Having reviewed the record, I find that Respondent is currently without authority to handle controlled substances in Texas, the State in which it holds its registration with the Agency, and is thus not entitled to maintain its DEA registration. I adopt the CALJ’s recommendation that I revoke Respondent’s registration and deny any pending renewal application. I make the following factual findings.

FINDINGS OF FACT

Respondent is the holder of DEA Certificate of Registration No. FH1729942, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy. GX 1 to Govt. Mot. On September 15, 2017, the TSBP issued an Order temporarily suspending Respondent’s Texas Pharmacy License #26701 “pending a contested case hearing on disciplinary action against the suspended license to be held . . . not later than . . . [90] days after the date of this Order.” GX 2 to Govt. Mot., at 4-5.¹ In its Order, the TSBP specifically

¹ The principal basis for the TSBP’s Order was the TSBP’s finding that Respondent’s pharmacist-in-charge filled prescriptions for controlled substances such as alprazolam 2mg and carisoprodol 350mg when he “should have

directed that Respondent “not operate as a pharmacy in this state in any manner that would allow receipt, distribution, or dispensing prescription drugs during the period said license is suspended.” *Id.* at 5. The TSBP also ordered Respondent to “immediately transfer all prescription drugs to a secured licensed pharmacy or other entity with the authority to legally possess prescription drugs, not later than September 22, 2017.” *Id.* There is no evidence in the record establishing that the TSBP ever lifted this suspension.

In its Order, the TSBP also stated that Respondent’s pharmacy license was “current through November 30, 2017.” *Id.* at 2. Neither the CALJ nor the parties addressed the fact that the Order stated that Respondent’s Texas pharmacy license would expire on November 30, 2017. As a result, I have reviewed the TSBP’s official website, and it confirms that Respondent’s current “License status” is “Expired.”² Accordingly, I find that Respondent currently does not

known the prescriptions . . . were invalid, i.e., not issued for a legitimate therapeutic purpose or valid medical need and/or prescription forgeries, due to prescription red flags factors indicating recurrent and readily-identifiable nontherapeutic prescribing and dispensing activity to a reasonable pharmacist.” *Id.* at 2-3.

² See www.pharmacy.texas.gov/dbsearch/phy_zoom.asp?id=26701&type=1. On November 9, 2017, the TSBP issued another suspension order stating that Respondent “agreed to the entry of this Order continuing the suspension of pharmacy number 26701 held by Respondent for an additional period of . . . [120] days from the date of entry of this Order pending a contested case hearing . . . against the suspended license” before “the State Office of Administrative Hearings.” TSBP Temporary Suspension Order #A-16-008-BS2 (*see* www.pharmacy.texas.gov/abo/detail/282232%20P26701%20Health%20Fit%20Pharmacy%20EDTSO%20A160008BS2%202017-11.pdf), at 1. The TSBP also repeated its directive that “Respondent shall not operate as a pharmacy in this state in any manner that would allow receipt, distribution, or dispensing prescription drugs during the period said license is suspended.” *Id.* The TSBP website does not show that the TSBP ever held a subsequent hearing regarding Respondent’s suspended pharmacy license or took any other action to lift the suspension.

I take official notice of the TSBP’s November 2017 enforcement action and the fact that the TSBP website currently shows that Respondent’s Texas pharmacy license is expired. Under the Administrative Procedure Act (APA), an agency “may take official notice of facts at any stage in a proceeding – even in the final decision.” U.S. Dept. of Justice, *Attorney General’s Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA’s regulations, Respondent is “entitled on timely request to an opportunity to show to the contrary.” 5 U.S.C. § 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.

possess a pharmacy license in the State of Texas, and thus does not possess authority to dispense controlled substances in the State in which it is registered with the DEA. *See id.* at 5.

DISCUSSION

Pursuant to 21 U.S.C. § 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (CSA), “upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” Also, DEA has long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner’s registration. *See, e.g., James L. Hooper*, 76 FR 71371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826 (4th Cir. 2012); *see also Frederick Marsh Blanton*, 43 FR 27616 (1978) (“State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.”).

This rule derives from the text of two provisions of the CSA. First, Congress defined “the term ‘practitioner’ [to] mean[] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C. § 802(21). Second, in setting the requirements for obtaining a practitioner’s registration, Congress directed that “[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. § 823(f).

Moreover, because “the controlling question” in a proceeding brought under 21 U.S.C. § 824(a)(3) is whether the holder of a DEA registration “is currently authorized to handle controlled substances in the [S]tate,” *Hooper*, 76 FR at 71371 (quoting *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner has lost his state authority by virtue of the State’s use of summary process and the State has yet to provide a hearing to challenge the suspension. *Bourne Pharmacy*, 72 FR 18273, 18274 (2007); *Wingfield Drugs*, 52 FR 27070, 27071 (1987). Thus, even assuming that Respondent’s pharmacy license is not expired but is still active and suspended, it is of no consequence that the TSBP has suspended Respondent’s pharmacy license and that Respondent may prevail in a future state hearing. What is consequential is the fact that Respondent is not currently authorized to dispense controlled substances in Texas, the State in which it is registered.³ *See* GX2 to Govt. Mot. (Sept. 15, 2017 TSBP Order), at 4-5. Accordingly, Respondent is not entitled to maintain its DEA registration.

I will therefore adopt the CALJ’s recommendation that I revoke Respondent’s registration and deny any pending applications to renew its registration. R.D. at 6. I will also deny any pending application to modify its registration, or any pending application for any other DEA registration in Texas, as requested in the Show Cause Order. Order to Show Cause, at 1.

³ In its brief opposing summary disposition, Respondent argued that the TSBP “abused it’s [sic] discretion in granting the temporary suspension . . . because the evidence shows that an agent of the DEA entrapped the Pharmacy in[to] committing a violation of the Controlled Substance[s] Act by intentionally failing to inform the Registrant that” it was filling prescriptions for a practitioner who “was not authorized to issue these prescriptions.” Resp. Br. at 2. Respondent’s claim relates to its challenge to the merits of the TSBP’s decision to suspend Respondent’s Texas pharmacy license, and I agree with the CALJ that Respondent has failed to show why or how this claim relates to whether Respondent is currently authorized to dispense controlled substances in the State of Texas. *See* R.D. at 3 n.1.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. §§ 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. FH1729942, issued to Health Fit Pharmacy, be, and it hereby is, revoked. I further order that any pending application of Health Fit Pharmacy to renew or modify the above registration, or any pending application of Health Fit Pharmacy for any other DEA registration in the State of Texas, be, and it hereby is, denied. This Order is effective immediately.⁴

Dated: May 17, 2018.

Robert W. Patterson,
Acting Administrator.

⁴ For the same reasons which led the TSBP to suspend Respondent's Texas pharmacy license, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

